UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

No. 20-cv-12057-RGS

JOSE LUIS GONZALEZ,

v.

JOHNSON & JOHNSON COMPANY, ETHICON, INC.,
a subsidiary of Johnson & Johnson,
LEMUEL SHATTUCK HOSPITAL, and JAMES G. PETROS, M.D.

ORDER ON MOTION FOR
JUDGMENT ON THE PLEADINGS

July 8, 2022

STEARNS, D. J.

Plaintiff Jose Gonzalez, a prisoner in the custody of the Massachusetts Department of Correction, filed this action against various defendants for post-operative complications arising out of a surgical procedure to repair an inguinal hernia performed at defendant Lemuel Shattuck Hospital on August 15, 2016.. In his Amended Complaint, Gonzalez also asserts medical malpractice claims against Dr. James Petros, the surgeon who performed the hernia repair, and products liability claims against defendants Johnson & Johnson Company (J&J) and Ethicon, Inc., the maker of the Prolene mesh used in the surgical implant. Dr. Petros has been dismissed from the case

(Dkt #46) and J&J and Ethicon have moved for judgment on the pleadings (Dkt #41).

BACKGROUND

Diagnosed with a "large left inguinal hernia," Gonzalez was admitted to Lemuel Shattuck on August 15, 2016, for surgery.[1] Am. Compl. ¶ 9; Dkt #49 at 31. Gonzalez's operative report indicates that a "4- x 2- inch piece of Prolene mesh" was sutured in place to secure his hernia. Dkt #49 at 30. Ethicon, a J&J subsidiary, does not dispute its manufacture of the accused mesh.

Gonzalez spent twelve days in post-operative recovery in Lemuel Shattuck's Intensive Care Unit during which he developed an infection. Am. Compl. ¶ 12. He was transferred to Boston Medical Center (BMC) and treated for sepsis (a "contaminated case"). *Id.* ¶¶ 13, 15. Gonzales contends that BMC surgeons conducted "life-saving and corrective surgery" to repair Lemuel Shattuck's "botched surgical procedure." Gonzalez accuses Lemuel Shattuck of using mesh "known to cause serious adverse health

[1] A hernia is defined as a "[p]rotrusion of a part or structure through the tissues normally containing it." STEDMAN'S MED. DICTIONARY 879 (28th ed. 2006). A left inguinal hernia would be on the left side of the pelvis and would involve either "the deep epigastric artery and the edge of the rectus muscle," or "the internal inguinal ring [which] passes into the inguinal canal." *Id.* at 880.

complications" as acknowledged by the Food and Drug Administration (FDA) in its recall of the Ethicon mesh.[2] *Id.* ¶¶ 14, 17. On September 4, 2019, Gonzalez underwent an "additional revision surgical procedure" to further repair his hernia. *Id.* ¶ 19.

Gonzalez initially filed this products liability/medical malpractice lawsuit in the Suffolk Superior Court, contending that "the result of being implanted with a medical device by the name of 'Prolene' . . . caused and resulted in serious life-threatening infections, Internal damage(s), permanent disfigurement . . . , chronic pain, emotional distress and mental anguish." *Id.* at 2. While he cites various statutes in a jurisdictional paragraph, Gonzalez's specific claims directed against J&J and Ethicon are for the defective design, manufacture, and labeling of the Prolene mesh used by Dr. Petros in the original hernia surgery. Gonzalez attaches eighty-five pages of documents to his Amended Complaint – a "hernia mesh fact sheet" unidentified as to its source; medical records from Lemuel Shattuck (operative and post-operative reports and a discharge summary dated September 3, 2016); and BMC records, including the operative notes for his

[2] Gonzalez avers that J&J and Ethicon are parties in federal multi-district litigation "over the use of several of their medical product[s] that are used to repair hernia injuries, which includes 'Prolene' that have resulted in personal injuries and serious complications like [he has experienced.]" *Id.* ¶ 18.

August 31, 2016 surgery, a report of a "trauma" procedure performed under local anesthesia on November 15, 2016, and notes of an additional surgical procedure dated November 3, 2017.[3]

The court allowed Dr. Petros's request to remand the case to the Superior Court for review by a medical malpractice tribunal (as required by state law, Gen. Laws ch. 231, § 61B). *See* Dkt # 16. On January 20, 2022, the Tribunal found for Dr. Petros, and gave Gonzalez with thirty days to post the statutory $6,000 bond. *See id.* When Gonzalez neither appealed nor posted the bond, the Superior Court dismissed his case. *See* Dkt #45-1 at 14. This court set a pretrial schedule on March 14, 2022, and J&J and Ethicon filed their dispositive motion on March 28, 2022. Gonzalez has filed no opposition to the motion.

DISCUSSION

Rule 12(c) of the Federal Rules of Civil Procedure permits a party to move for judgment on the pleadings at any time "[a]fter the pleadings are closed," if the motion does not delay the trial. A Rule 12(c) motion differs from a Rule 12(b)(6) motion in that it implicates the pleadings in their

[3] Gonzalez amended his Complaint in the Superior Court prior to J&J and Ethicon's 11/18/20 removal of this case to federal court. *See* Dkt #1-3. J&J's counsel supplied the missing attachment to this court on June 1, 2022, which the court has sealed as all but three pages are medical records. *See* Dkt #49.

entirety. "In the archetypical case, the fate of such a motion will depend upon whether the pleadings, taken as a whole, reveal any potential dispute about one or more of the material facts." *Gulf Coast Bank & Tr. Co. v. Reder*, 355 F.3d 35, 38 (1st Cir. 2004). Because fact discovery remains open in this case until September 2, 2022, and defendants have filed no previous motion to dismiss, the court will treat the motion as one under Rule 12(b)(6).

"The sole inquiry under Rule 12(b)(6) is whether, construing the well-pleaded facts of the complaint in the light most favorable to the plaintiffs, the complaint states a claim for which relief can be granted." *Ocasio-Hernandez v. Fortuno-Burset*, 640 F.3d 1, 7 (1st Cir. 2011). In most circumstances, the plaintiff need not demonstrate a "heightened fact pleading of specifics," but rather must present "only enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqba*l, 556 U.S. 662, 678 (2009). Although the court must accept well-pleaded facts as true, conclusory allegations are not entitled to any presumption of truth. *Id.* at 678-679.

While Gonzalez alludes to numerous federal and Massachusetts statutes and general theories of law at various places in his Amended

Complaint, he identifies only three recognizable claims of product liability against J&J and Ethicon – that the Prolene mesh was defectively designed and manufactured, and that defendants failed to adequately warn him and his surgeon of the foreseeable risks of harm.[4] *See generally* Mass. Gen. Laws, ch. 106, § 2-314*;* Restatement (Third) of Torts: Products Liability § 2 at 14 (1998) ("[A] product is defective when, at the time of sale or distribution, it contains a manufacturing defect, is defective in design, or is defective because of inadequate instructions or warnings.").

Defective Design

Manufacturers have "the duty to design [their] product[s] so that [they are] reasonably fit for the purpose for which [they were] made." *Smith v. Ariens Co.*, 375 Mass. 620, 623 (1978). "For a product to be defective, it must be 'made according to an unreasonably dangerous design' and does not meet a consumer's reasonable expectation as to its safety." *Niedner v. Ortho-McNeil Pharm., Inc.*, 90 Mass. App. Ct. 306, 312 (2016), quoting *Everett v.*

[4] Gonzalez does not plead a viable consumer protection claim under Gen. Laws ch. 93A, as he fails to plead the proper elements or reference the mandatory pre-suit demand letter. *See United States ex rel. Gagne v. City of Worcester*, 565 F.3d 40, 45 (1st Cir. 2009) ("[A Chapter 93A] complaint must specify the time, place, and content of an alleged false representation."). Similarly, Gonzalez directs the court to the Massachusetts Tort Claims Act, Gen. Laws ch. 258, ¶ 2, however, the Act applies to negligent acts of "public employers" – and not to private party defendants.

Bucky Warren, Inc., 376 Mass. 280, 290 (1978). To plead a design defect, a plaintiff must demonstrate "(1) the manufacturer's failure to exercise a reasonable degree of care under the circumstances; (2) proximate causation; and (3) injury and/or loss." *Geshke v. Crocs, Inc.,* 889 F. Supp. 2d 253, 261 (D. Mass. 2012), citing *Ulwick v. DeChristopher*, 411 Mass. 401, 408 (1991). However, Gonzalez's Amended Complaint fails to identify any defective aspect of the Prolene mesh or its causal relation to his injuries – he recited only that Prolene mesh was used in his surgery, that he developed a subsequent infection, and that others have sued these same defendants alleging the Prolene mesh is defective.[5] While he quotes portions of the medical record that refer to possible "Fournier Gangrene" (Am. Compl. ¶ 12), "sepsis" (*Id.* ¶ 13), and "enterocutaneous fistula" (*Id.* ¶ 16), he fails (consistent with the medical records he cites) to connect these conditions the design of the mesh. The design defect portion of Gonzalez negligence claim will therefore be dismissed.

[5] While defendants also argues that Gonzalez has failed to plead a safer, alternative design, while such "proof . . . may ultimately be required, it does not appear that Massachusetts law would require a plaintiff to plead the existence of an alternative design." *Taupier v. Davol* , 490 F. Supp 3d 430, 446 (D. Mass. 2020), citing *Osorio v. One World Techs., Inc.,* 659 F.3d 81, 87 (1st Cir. 2011) (concluding that *Smith v. Ariens*, 375 Mass. 620 (1978) "suggests that Massachusetts product liability law may tolerate a finding of design defect even in the absence of evidence supporting the existence of a feasible alternative design.").

Manufacturing Defect

Gonzalez also avers in his Amended Complaint that defendants' Prolene mesh product was defectively manufactured. *See* Am. Compl. ¶¶ 23(b) and 30(b). "In order to establish a manufacturing defect, a plaintiff must demonstrate that there is a 'deviation from the design [that] rendered the product unreasonably dangerous and therefore unfit for its ordinary purposes.'" *Burnham v. Wyeth Labs. Inc.*, 348 F. Supp. 3d 109, 112 (D. Mass. 2018) (alteration in original), quoting *Back v. Wickes Corp.*, 375 Mass. 633, 641 (1978). Under Massachusetts law, a manufacturing defect occurs where "a particular product[,] rather than a line of products, is alleged to be defective because of negligence in the manufacturing process." *Smith v. Ariens Co.*, 375 Mass. 620, 626 (1978). The Amended Complaint is devoid of any allegation that the Ethicon Prolene mesh patch was manufactured in a manner that negligently deviated from its intended design. Accordingly, this portion of Gonzalez's negligence claim will also be dismissed.

Defective Warning/Failure to Warn

Finally, Gonzalez maintains that J&J and Ethicon failed to warn him, Dr. Petros, or Lemuel Shattuck "of the risk or likelihood of infections and other medical problems or complications with the use of 'Prolene' Mesh product." *See* Am. Compl. ¶¶ 23(d) and 30(d). Under Massachusetts law, "a

manufacturer can be found liable to a user of the product if the user is injured [because of] the failure of the manufacturer to exercise reasonable care in warning potential users of hazards associated with use of the product." *Laaperi v. Sears, Roebuck & Co., Inc.*, 787 F.2d 726, 729 (1st Cir. 1986). As a defense, the manufacturer may rely on the "learned intermediary" doctrine, which "provides that 'a . . . manufacturer's duty to warn of dangers associated with its product runs only to the physician; it is the physician's duty to warn the ultimate consumer.'" *Calisi v. Abbott Labs.*, 2013 WL 5441355, at *3 (D. Mass. Sept. 27, 2013), quoting *Cottam v. CVS Pharm.*, 436 Mass. 316, 321 (2002). This doctrine is pinned on the reasoning that "the prescribing physician, as the 'learned intermediary' standing between the manufacturer and the consumer/patient, is generally in the best position to evaluate the potential risks and benefits of [the product's use] and to advise the patient accordingly." *Garside v. Osco Drug, Inc.*, 976 F.2d 77, 80 (1st Cir. 1992).

Courts use a burden-shifting framework "[t]o determine whether a plaintiff can make a prima facie case of negligence despite imposition of the learned intermediary rule." *Langlois v. Am. Med. Sys., Inc.*, 462 F. Supp. 3d 1, 3 (D. Mass. 2020). Under this framework, "the plaintiff carries the initial burden of producing sufficient evidence that the defendant manufacturer

failed to warn of a non-obvious risk about which the manufacturer knew or should have known . . . . " *Garside*, 976 F.2d at 81. Gonzalez fails to offer any description of the warning and instructions that Ethicon or J&J provided or should have provided Dr. Petros other than an ever-present risk of infection, which is plainly set out in the instructions. *See* Am. Answer (Dkt #11-1 at 2) ("Prolene can cause potentiation of infection."). [6]

ORDER

For the foregoing reasons, the Motion to Dismiss is ALLOWED.

SO ORDERED.

/s/ Richard G. Stearns
UNITED STATES DISTRICT JUDGE

[6] Gonzalez also attempts to plead (by bare mention) breach of express warranty and the implied warranty of merchantability. *See* Am. Compl. ¶ 31. However, his failure to plead a viable defective design or failure to warn claim precludes resort to these theories. *See Evans v. Lorillard Tobacco Co.*, 465 Mass. 411, 422 (2013); *Hebert v. Vantage Travel Serv., Inc.*, 444 F. Supp. 3d 233, 245-246 (D. Mass. 2020).